non-elected claims 10-15 have been cancelled. Upon entry of the foregoing amendments claims 1-4, 6-9 and 16-20 are pending in the present application.

III. The Objection to the Specification

In the Office Action at pages 2 and 3, the Examiner has objected to the specification because it allegedly contains embedded hyperlinks and/or other forms of browser executable code. Applicants have accommodated this objection by amendment of the specification to remove all "http://" prefixes and remove underlining. No new matter was added by way of this amendment.

A URL is not considered to be browser executable code if it is not either preceded with *http://* or placed between the symbols "< >." M.P.E.P. § 608.01, page 600-60, Examiner Note. As such, the URLs present in the application, as amended, are not browser executable code, and would not be interpreted by a browser as a link to another web site when the document is placed on the USPTO web site. Reconsideration and withdrawal of this objection are respectfully requested.

IV. Rejection of Claims Under 35 U.S.C. § 101

In the Office Action at pages 3-5, the Examiner has rejected claims 1-4, 6-9 and 16-20 under 35 U.S.C. § 101, for allegedly lacking a patentable utility. Applicants respectfully traverse this rejection.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "gene mapping, marker assisted introgression of traits, physical mapping, etc." Office Action, at page 4. Moreover, other utilities are set forth in the

specification. *See* pages 44-93 under "Exemplary Uses of the Agents of the Invention." However, the Examiner contends that none of these utilities constitute a "substantial" or "specific" utility. Applicants respectfully disagree with this assertion.

It is well established that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.,* 724 F.2d 951, 958, 220 U.S.P.Q. 592, 298 (Fed. Cir. 1983). The present specification describes many objectives that are met by the present invention. In addition to the utilities described by the Examiner (quoted above), the claimed nucleic acid molecules are useful for obtaining protein molecules, determining the presence and/or identity of polymorphisms, measuring the levels of an mRNA in a sample, determining the location of a corresponding DNA sequence on a physical or genetic map, probing for other molecules, generating primers, obtaining other nucleic acid molecules from the same species, obtaining related protein coding sequences, obtaining promoters and other flanking genetic elements, screening cDNA genomic libraries, obtaining nucleic acid homologs, detecting and characterizing gene expression, etc. *See* specification at page 44-93 under "Exemplary Uses of the Agents of the Invention."

Many of these uses are directly analogous to a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell or organism. Significantly, the utility of the microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.,* the claimed nucleic acid molecules may be used to identify and characterize other nucleic acid molecules within a sample, cell or organism. Such utility is indistinguishable from the legally sufficient utility

of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather the Examiner attempts to undermine the existing utilities by stating, "[t]he claimed nucleic acid compounds are not supported by a specific asserted utility because the disclosed uses of the nucleic acids are generally applicable to rice genomic nucleic acid." Office Action, at page 4. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stifung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Moveover, this position offends the sensibilities. For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.,* hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 306 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.,* 289 U.S. 178, 199, 17 U.S.P.Q. 154, 163 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

As noted above, the claimed nucleic acid molecules have many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid

sequences may generally be used to identify and locate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit a ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid sequences exhibit the requisite utility under 35 U.S.C. § 101.

Surprisingly, the Examiner notes that the credibility of the presently asserted utilities has not been assessed. Office Action, at page 5. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 752 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact

made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...").

Here the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1-4, 6-9 and 16-20 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

V. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

In the Office Action, at pages 5-6, the Examiner has rejected claims 1-4, 6-9 and 16-20 as not being enabled by the specification because the claimed invention allegedly lacks utility. Applicants respectfully traverse this rejection. This rejection has been overcome by the foregoing arguments regarding utility. Thus this rejection under 35 U.S.C. § 112, first paragraph is improper. Reconsideration and withdrawal are respectfully requested.

VI. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

In the Office Action, at page 6, the Examiner has rejected claims 1-4, 6-9 and 16-20 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description. Applicants respectfully traverse this rejection.

The Examiner asserts that Applicants have not adequately described the claimed genus of nucleic acid molecules because Applicants allegedly have not adequately described a representative number of claimed nucleic acid molecules. Applicants respectfully disagree with this contention.

An adequate written description of a genus of nucleic acids, as recited in the claims, may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772

F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, in order for Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules be disclosed. *In re Alton,* 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996) (if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification).

The Examiner further contends that the skilled artisan cannot envision the detailed chemical structure of the claimed polynucleotides. The Examiner seems to assert that proper written description support for a claim directed to a nucleic acid sequence requires nothing less than the actual disclosure of every sequence encompassed by that claim. In support of these propositions, the Examiner relies on *Regents of the University of California v. Eli Lilly and Co*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). Applicants respectfully disagree. In *Eli Lilly* the court found that claims to a vertebrate cDNA coding for insulin were inadequately described. However, the present case is clearly different than *Eli Lilly*. Specifically, the present claims "distinguish the claimed genus from others" and define "structural features commonly possessed by members of the genus that distinguishes them from others," unlike the claims at issue in *Eli Lilly*. *Id.* at 1568-69.

In particular, Applicants have provided a detailed chemical structure (SEQ ID NO: 1) that distinguishes that claimed genus from other nucleic acid molecules. Moreover, nucleic acid molecules falling within the scope of the present claims are readily identifiable in that they comprise a nucleic acid molecule having the sequence of SEQ ID NO: 1 and complements thereof. The fact that the nucleic acid molecules may comprise

additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed through the present specification. Thus, there is no deficiency in the written description support for claims 1-4, 6-9 and 16-20 under 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

VII. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

In the Office Action at page 9, the Examiner has rejected claims 1-4, 6-9 and 16-20 under 35 U.S.C. § 112, first paragraph for allegedly lacking enabling support commensurate with the scope of the claims. Applicants respectfully traverse this rejection.

Due to the sequence election imposed by the Examiner, present claims 1-4, 6-9 and 16-20 relate to substantially purified molecules having the sequence of SEQ ID NO: 1, and fragments and complements thereof. The Examiner admits that the specification is enabling for nucleotides of elected SEQ ID NO: 1. Office Action at pages 8-9. Therefore, Applicants assert that this rejection of claims 1-4, 6-9 and 16-20 under 35 U.S.C. § 112, first paragraph, is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

VIII. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

In the Office Action at page 9, the Examiner has rejected claims 1-4, 6-9 and 16-20 under 35 U.S.C. § 112, second paragraph for use of the term "complements." Applicants respectfully traverse this rejection.

The Examiner asserts that claims 1-4, 6-9 and 16-20 are indefinite due to the use of the term "complements." Applicants disagree with this assertion. On page 19, lines 7-10, Applicants have clearly disclosed what is meant by the term "complement." As such, one of ordinary skill in the art could readily determine the metes and bounds of the claim. *Seattle Box Co. v. Industrial Crating and Packing, Inc.*, 731 F.2d 818, 826, 221 U.S.P.Q. 568, 574 (Fed. Cir. 1984) (a decision on whether a claim is invalid under §112, second paragraph, requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification). Therefore, this portion of the rejection is improper.

The Examiner further asserts that the recitation of "Table 1" in claim 16 makes the claim indefinite because the information in the Table may change over time. This assertion is incorrect as a matter of law. First, claims should be read in light of the specification. If the specification clearly and unambiguously defines the disputed terminology then reliance on extrinsic evidence (e.g., subsequently published database entries or scientific references) to construe the claim language is legally incorrect. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 39 U.S.P.Q.2d 1573 (Fed. Cir. 1996). Moreover, definiteness in claims is determined as of the filing date, and it is error to rely on subsequent developments and publications to find uncertainty in the terms of a patent. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983) *cert. denied,* 469 U.S. 851 (1984). Table 1 of the specification clearly defines what is meant by "a rice protein or fragment thereof from Table 1" so that one of ordinary skill in the art would know what is encompassed by the claims. As such, the Examiner's rejection of claim 16 is improper.

Finally, the Examiner asserts that claims 6-9 are indefinite because they depend from a canceled claim. Claims 6-9 have been amended so that they no longer depend on a cancelled claim; therefore, this portion of the rejection has been accommodated. Reconsideration and withdrawal of the Examiner's rejection of claims 1-4, 6-9 and 16-20 under 35 U.S.C. § 112, second paragraph, are respectfully requested.

IX. Rejection of Claims Under 35 U.S.C. § 102(a) and (b)

REJECTION OF CLAIMS 1-2 and 17-18

In the Office Action at page 10, the Examiner has rejected claims 1-2 and 17-18 under 35 U.S.C. § 102(b) as allegedly being anticipated by Birren *et al.* (Genbank accession No. AC005922, 11/14/98). Applicants respectfully traverse this rejection. The present application claims priority to U.S. Provisional Application No. 60/144,351, filed 7/20/99. Therefore, Birren *et al.*, which was published on 11/14/98, is not proper prior art under 35 U.S.C. § 102(b). Reconsideration and withdrawal of this rejection are respectfully requested.

REJECTION OF CLAIM 3

In the Office Action at page 10, the Examiner has rejected claim 3 under 35 U.S.C. § 102(b) as allegedly being anticipated by Su *et al.* (Genbank accession No. AF015462, 7/16/98). Applicants respectfully traverse this rejection.

The sequence disclosed by Su *et al.* does not exhibit complete complementarity to SEQ ID NO: 1, as required by claim 3 (which depends from claim 2). As such, the sequence disclosed in Su *et al.* can not anticipate claim 3. Reconsideration and withdrawal of this rejection are respectfully requested.

REJECTION OF CLAIMS 4 AND 9

In the Office Action at page 11, the Examiner has rejected claims 4 and 9 under 35 U.S.C § 102(b) as being anticipated by Alonso *et al.* (Genbank accession No. X74737, 1/21/99). Applicants respectfully traverse this rejection.

The present application claims priority to U.S. Provisional Application No. 60/144,351, filed 7/20/99. Therefore, Alonso *et al.*, which was published on 1/21/99, is not proper prior art under 35 U.S.C. § 102(b). Reconsideration and withdrawal of this rejection are respectfully requested.

REJECTION OF CLAIM 6

In the Office Action at page 11, the Examiner has rejected claim 6 35 U.S.C. § 102(a), as allegedly being anticipated by Wright *et al.* (Genbank accession No. AA235275, 3/27/00). Applicants respectfully traverse this rejection.

The sequence disclosed by Wright *et al.* is not a fragment nucleic acid having from about 50 to about 100 nucleotide residues of SEQ ID NO: 1, as required by claim 6 (which depends on claim 16). Moreover, the sequence of Wright *et al.* does not encode a rice protein as required by claim 6 (which depends from claim 16). As such, the sequence disclosed by Wright *et al.* cannot anticipate claim 6. Reconsideration and withdrawal of this rejection are respectfully requested.

REJECTION OF CLAIMS 7-8

In the Office Action at page 11, the Examiner has rejected claims 7-8 under 35 U.S.C. § 102(b), as allegedly being anticipated by Baba *et al.* (Genbank accession No. E03434, 9/29/97). Applicants respectfully traverse this rejection.

The sequence disclosed by Baba *et al.* is not a fragment nucleic acid having from about 50 to about 100 nucleotide residues of SEQ ID NO: 1, as required by claims 7-8 (which

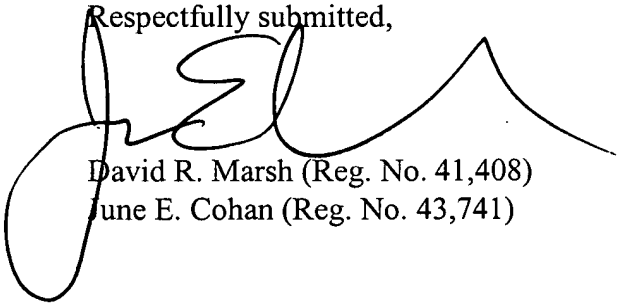
depend from claim 16). Moreover, the sequence of Baba *et al.* does not encode a rice protein as required by claims 7 and 8 (which depend from claim 16). As such, the sequence disclosed by Wright *et al.* cannot anticipate claims 7 or 8. Reconsideration and withdrawal of this rejection are respectfully requested.

X. Summary

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,



David R. Marsh (Reg. No. 41,408)
June E. Cohan (Reg. No. 43,741)

Date: December 21, 2001

Arnold and Porter
555 Twelfth Street
Washington, DC 20004-1206
(202) 942-5000 telephone
(202) 942-5999 facsimile

Version with markings to show changes made

In the Specification at page 3, line 21 through page 4, line 5:

Similarity analysis includes database search and alignment. Examples of public databases include the DNA Database of Japan (DDBJ)([http://]www.ddbj.nig.ac.jp/); [Genebank] Genbank ([http://]www.ncbi.nlm.nih.gov/web/Genbank/Index.[htlm] html); and the European Molecular Biology Laboratory Nucleic Acid Sequence Database (EMBL) ([http://]www.ebi.ac.uk/ebi_docs/embl_db.html). A number of different search algorithms have been developed, one example of which are the suite of programs referred to as BLAST programs. There are five implementations of BLAST, three designed for nucleotide sequences queries (BLASTN, BLASTX, and TBLASTX) and two designed for protein sequence queries (BLASTP and TBLASTN) (Coulson, *Trends in Biotechnology, 12*:76-80 (1994); Birren, *et al.*, *Genome Analysis, 1*:543-559 (1997)).

In the Specification at page 8, lines 4-14:

A characteristic feature of a large scale shotgun sequencing project is that the sequence data can be processed and assembled into contiguous sequences (contigs), which represent a reconstruction of the original genome sequence from the cloned fragments. Likewise, individual Bacterial Artificial Chromosome (BAC) clones within a BAC library can be shot gun sequenced and these data can be assembled into contigs within each clone. Programs are available in the public domain that can analyze the sequence output and assemble the sequences into larger sequence regions representing contiguous sequences of the target genome. Examples of such programs can be found at, for example, [http://]genome.wustl.edu/gsc, [http://]www.sanger.ac.uk, and [http://]www.mbt.washington.edu. An example of sequence reading program is Phred

([http://]www.mbt.washington.edu). Phred reads DNA sequencer trace data, calls bases, assigns quality values to the bases, and writes the base calls and quality values to output files.

In the Specification at page 8, line 15 through page 9, line 8:

The process of assembling DNA sequence fragments generally involves three phases; the overlap phase, the layout phase and the multi-alignment, or consensus, phase. In the overlap phase, each fragment is compared against every other fragment to determine if they share a common subsequence, an indication that they were potentially sampled from overlapping stretches of the original DNA strand. Pairs of fragments are compared in two ways; 1) with both fragments in the same relative orientation, and 2) with one of the fragments having been reverse complemented. In the layout phase, a series of alternate assemblies or layouts of the fragments based on the pairwise overlaps is generated. A layout specifies the relative locations and orientations of the fragments with respect to each other and is typically visualized as an arrangement of overlapping directed lines, one for each fragment. The general criterion for the layout phase is to produce plausible assemblies of maximum likelihood. In this manner, it can be determined if there is more than one way to put the pieces together and if different solutions appear equally plausible. In such a case, one would return to the lab and obtain additional information to resolve the ambiguity. The multi-alignment, or consensus, phase uses more information than just the pairwise alignments in the layout. The sequences of all the fragments in a layout are simultaneously aligned, giving a final set of contigs representing regions of the target genome. An example of an assembly program is PHRAP, which can be found at http://chimera.biotech.washington.edu/UWGC/tools/phrap.htm.

In the claims

Sub E1 1. (Once amended) A substantially purified nucleic acid molecule having a nucleic acid sequence [selected from the group consisting] of SEQ ID NO: 1 [through SEQ ID NO: 69652] or complements thereof.

2. (Twice amended) A substantially purified nucleic acid molecule comprising a fragment nucleic acid having from about 50 to about 100 nucleotide residues; wherein said fragment nucleic acid exhibits complete complementarity to a second nucleic acid molecule having a nucleic acid sequence [selected from the group consisting] of SEQ ID NO: 1 [through SEQ ID NO: 69652 and] or complements thereof.

6. (Once amended) The substantially purified nucleic acid molecule according to claim [5] 16, wherein said rice protein or fragment thereof is a homologue of a dicot plant protein or fragment thereof.

7. (Once amended) The substantially purified nucleic acid molecule according to claim [5] 16, wherein said rice protein or fragment thereof is a homologue of a non-rice monocot plant protein or fragment thereof.

Sub E2 8. (Once amended) The substantially purified nucleic acid molecule according to claim [5] 16, wherein said rice protein homologue or fragment thereof is a homologue of a non-rice cereal protein or fragment thereof.

9. (Once amended) The substantially purified nucleic acid molecule according to claim [5] 16, wherein said rice protein or fragment thereof is a homologue of a bacterial protein or fragment thereof.

16. (Once amended) A substantially purified nucleic acid molecule encoding a rice protein or fragment thereof from Table 1, wherein said substantially purified nucleic acid molecule comprises a fragment nucleic acid molecule having from about 50 to about 100 nucleotide residues of [a] the nucleic acid molecule [selected from the group consisting] of SEQ ID NO: 1 [through SEQ ID NO: 69652].

Sub E3 17. (Once amended) ~~A~~ substantially purified nucleic acid molecule having between 90% and 100% sequence identity with [a] the second nucleic acid molecule [selected from the group consisting] of SEQ ID NO: 1 [through SEQ ID NO: 69652 and] or complements thereof.